REMARKS

Claims 1-8 were pending. Claims 1, 4, and 8 have been amended. Claim 2 has been cancelled. Therefore, claims 1, and 3-8 will be pending upon entry of the instant amendment.

No new matter has been added. Support for the amendments to claim 1 can be found in claim 2 as originally filed. Support for the amendment to claims 4 and 8 can be found, for example, in the specification as originally filed at page 9, lines 13-15.

Cancellation of and/or amendments to the claims should in no way be construed as an acquiescence to any of the Examiner's objections and/or rejections. The cancellation of the claims and/or amendments to the claims are being made solely to expedite prosecution of the above-identified application. Applicants reserve the option to further prosecute the same or similar claims in the present or another patent application. The amendments made to the claims are not related to any issues of patentability.

Rejection of Claims 1-3 under 35 U.S.C. § 102 (b)

Claims 1-3 were rejected under 35 U.S.C. § 102(b) as being anticipated by Lomen (EP 0 068 838). Applicants respectfully disagree and traverse the rejection. Claim 2 has been cancelled, thus rendering its rejection moot.

Claim 1 is directed to a pharmaceutical composition comprising a blend of granule and extragranule material, wherein said granule is comprised of ibuprofen and a narcotic analgesic in a single phase. Claim 3 is directed to a tablet comprising the compressed composition.

According to the Examiner, Lomen describes a composition comprising a combination of a narcotic analagesic and ibuprofen or flurbiprofen, and a method for making a tablet by preparing a powder mixture, granulating, adding a lubricant and pressing into tablets. Applicants submit that Lomen does not teach or suggest a pharmaceutical composition comprising granule and extragranule material, wherein the extragranule material comprises an excipient, as currently claimed. In contrast, Lomen only describes compositions comprising a granule and a lubricant. Therefore, Applicants respectfully request that this rejection of the claims under 35 U.S.C. § 102 (b) be withdrawn.

Rejection of Claims 4-8 under 35 U.S.C. § 103(a)

Claims 4-8 are rejected under 35 U.S.C. § 103 (a) as being unpatentable over Lomen and Haas (US 4,859,704).

Claim 4 is directed to a pharmaceutical tablet composition comprising an effective amount of ibuprofen; an effective amount of hydrocodone; colloidal silicon dioxide wherein the weight of the colloidal silicon dioxide is provided in a range, of the total weight of the tablet, of about 0.5% to about 3%; a filler selected from the group consisting of microcrystalline cellulose and powdered cellulose; a disintegrant selected from the group consisting of croscarmellose sodium, crospovidone, and sodium starch glycolate; a binder consisting of an alkylhydroxy methylcellulose wherein the weight of the binder is provided in a range, of the total weight of the tablet composition, of about 2% to less than 6%; a starch provided in a weight range, of total weight of the tablet composition, of about 11% to about 28%; and a lubricant wherein the lubricant is provided in an amount less than 1% by weight of the total weight of the tablet, wherein the tablet comprises a compressed blend of a granule and extra granule material wherein the granule comprises at least a portion of the ibuprofen, at least a portion of the narcotic analgesic, a portion of the colloidal silicon dioxide, a portion of the disintegrant, and a portion of the starch and the weight of the extra granule material is provided in a range of up to about 25% of the weight of the whole tablet, wherein said tablet is substantially free of lactose. Claims 5-7 are dependent upon claim 4 and thus contain all of its elements.

Claim 8 is directed to a pharmaceutical tablet composition comprising an effective amount of ibuprofen wherein the weight of the ibuprofen is provided in a range, of the total weight of the tablet composition, of up to about 50%; an effective amount of hydrocodone; colloidal silicon dioxide provided in a range, by total weight of the tablet composition, of about 1.5% to about 2%; microcrystalline cellulose provided in a range, of the total weight of the tablet composition, of about 15% to about 25%; a disintegrant selected from the group consisting of croscarmellose sodium and crospovidone wherein the weight of the disintegrant is provided in a range, of the total weight of the tablet composition, of about 6 to about 8%; a binder consisting of an alkylhydroxy methylcellulose wherein the weight of the binder is provided in a range, of the total weight of the tablet composition, of about 3 % to about 4 %; corn starch wherein the weight of the corn starch is provided in a range, of the total weight of the tablet composition, of about 11 to about 17 %; and a lubricant wherein the weight of the lubricant is provided in an amount less than 1% by weight of the total weight of the tablet, wherein said tablet is substantially free of lactose.

As described above, according to the Examiner, Lomen describes a composition comprising a combination of a narcotic analagesic and ibuprofen or flurbiprofen, and a method for making a tablet by preparing a powder mixture, granulating, adding a lubricant and pressing into tablets. Lomen does not teach or suggest compositions which are substantially free of lactose, such as claimed by Applicant. In contrast, each of the tablets described by Lomen contain a substantial amount of lactose.

Haas is directed to alkali salts of ibuprofen. According to the Examiner, Haas describes a composition comprising ibuprofen in combination with other medications. Further according to the Examiner, Haas describes the use of silicon dioxide, binder, sodium starch glycolate, lubricant and filler in an oral dosage tablet. In addition, the tablets described by Haas also contain a substantial amount of lactose.

Although the Examiner argues that "where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation," Applicants submit that Haas, either alone or in combination with Lomen, fails to teach or suggest the "general conditions" of Applicants' claims, let alone the specific claim elements. Furthermore, each of the references fail to teach or suggest a pharmaceutical composition substantially free of lactose. Applicants therefore respectfully request that this rejection of claims 4-8 under 35 U.S.C. § 103 (a) be withdrawn.

Rejection of Claims 4-8 under 35 U.S.C. § 103(a)

Claims 4-8 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Lomen and U.S. 4,844,907 to Elger *et al.* ("Elger *et al.*"). Applicants respectfully disagree and traverse the rejection.

Lomen describes tablets comprising ibuprofen, morphine sulfate, lactose, corn starch, magnesium stearate, and light liquid petroleum in a single phase. According to the Examiner, Elger teaches tablet compositions which can be made by wet granulating the active ingredients and excipients, including microcrystalline cellulose, starch, binder, and glidants, anti-adherents, and disintegrants. The Examiner notes that Elger does not teach the amounts of actives, excipients and relative proportions of the granule and extra granule material. The Examiner states that "no criticality is seen in the particular limitations."

Applicants respectfully disagree. It is only through the use of hindsight can the Examiner declare the particular combination and amount of ingredients of Applicants' invention to be lacking "criticality." An ordinarily skilled artisan would not have been motivated to use the teachings of Elger *et al.* to modify Lomen because Elger *et al.*

teaches away from using a narcotic analagesic in a single phase with ibuprofen with the ingredients described in Elger *et al.*. In the "Comparative Example," Elger *et al.* describe an unsuccessful composition of tablets comprising ibuprofen, codeine phosphate, microcrystalline cellulose, croscarmellose sodium, hydroxypropylmethyl cellulose, and magnesium stearate. The tablets were manufactured using a wet granulation process and the ibuprofen and the codeine phosphate were in a single-phase dosage. However, Elger *et al.* state that these tablets had "poor disintegration times, poor crushing strengths, and exhibited sticking problems" (col. 6, lines 8-10).

It is therefore only through the improper use of hindsight reconstruction that the Examiner is able to combine Lomen with Elger *et al.* In *Rouffet* the CAFC stated:

> [b]ecause the Board did not explain the specific understanding or principle within the knowledge of a skilled artisan that would motivate one with no knowledge of Rouffet's invention to make the combination, this court infers that the examiner selected these references with the assistance of hindsight. ***This court forbids the use of hindsight in the selection of references that comprise the case of obviousness.*** See In re Gorman, 933 F.2d 982, 986, 18 U.S.P.Q. 2D (BNA) 1885, 1888 (Fed Cir. 1991). Lacking a motivation to combine references, the Board did not show a proper prima facie case of obviousness. This court reverses the rejection over the combination of King, Rosen, and Ruddy, (emphasis added).

In re Rouffet at 149 F.3d 1350, 47 U.S.P.Q.2d, BNA 1453 (Fed. Cir. 1998).

The CAFC has ruled that "[a] holding that combination claims are invalid based merely upon finding similar elements in separate prior art patents would be 'contrary to statute and would defeat the congressional purpose in enacting Title 35.' " *SmithKline Diagnostics*, 859 F.2d. at 886-887 (citing *Panduit Corp v. Dennison Mfg. Co.*, 810 F.2d 1561, 1577 (Fed. Cir. 1987)) (citations omitted).

Applicants submit that it is only through the use of hindsight that the particular ingredients and quantities would be selected such that the desirable qualities of good compression strength and superior disintegration were obtained in a single phase tablet. The tablets described by Lomen comprise substantially different fillers, binders, and disintegrants and one of ordinary skill in the art would not have been motivated to use the ingredients described in Elger *et al.* because Elger *et al.* teaches away from using the ingredients in single phase tablets as described in Lomen. Applicants therefore

respectfully request reconsideration and withdrawal the rejection of claims 4-8 under 35 U.S.C. § 103 (a).

SUMMARY

In view of the foregoing, entry of the amendments and remarks presented herein, favorable reconsideration and withdrawal of the rejections, and allowance of this application with all pending claims are respectfully requested. If a telephone conversation with Applicants' Attorney would expedite prosecution of the above-identified application, the Examiner is invited to call Applicants' attorney at (617) 227-7400.

Date: November 25, 2003

LAHIVE & COCKFIELD, LLP
Attorneys at Law

By _____

Cynthia M. Soroos
Reg. No. 53,623
28 State Street
Boston, MA 02109
(617) 227-7400
(617) 742-4214